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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 11/20/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/380,546

Applicant(s)

WALLACH ET AL.

Examiner

Brian Whiteman

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): 112 second paragraph rejection for claims 49-52, 59, 65, 66.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: 45-48, 55, 56, 58 and 63-68.Claim(s) rejected: 44, 49-54, 57, 59, and 69- 71.Claim(s) withdrawn from consideration: 60 and 61.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☒ Other: See Continuation Sheet

Continuation of 5. does NOT place the application in condition for allowance because: Proposed claim 69 recites "A method in accordance with claim 44", however, claim 44 is directed to "A molecule comprising a DNA sequence". Thus, new claim 69 is object to because it does not further limit claim 44.

The amendment has been entered, however the following objections/rejections remain or are applicable:

Claims 45-48, 55, 56, 58, 63-68 are objected to for the objection of record in paper no. 24. Furthermore, claim 69 is objected to for not further limiting the claim that it is dependent therefrom for the reasons set forth above.

Claims 44, 49-54, 57, and 59 would remain rejected under 112 enablement for the rejection of record in paper no. 24. More specifically, the as-filed specification or applicants' traversal do not provide sufficient guidance and/or factual evidence for one skilled in the art to make and/or use an analog which differs from the sequence of claim 44(a) by no more than ten changes in the amino acid sequence of (a), each said change being a substitution, which analog is capable of binding to one or more of MORT-1 and MACH. The as-filed specification fails to provide sufficient guidance for one skilled in the art to reasonably determine which amino acids are considered essential for binding to either MORT-1 or MACH. The state of the art teaches the unpredictability of predicting the biological activity of a nucleotide sequence based on its primary structure (See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991, Chiu, and Ngo cited in paper no. 24). Furthermore, one skilled in the art understand that the substitution of one amino acid can change the biological activity of amino acid sequence (See paper no. 24). Thus, the as-filed specification fails to provide sufficient guidance for making the sequence in claim 44, 54 and claims dependent therefrom encompassing an analog of DNA molecule SEQ ID NO: 1 or 3 and the amino acid sequence in SEQ ID NO: 2 or 4, when the claimed sequence has no more than ten changes in the amino acid sequence, each said change being a substitution, which analog is capable of binding to one or more of MORT-1 and MACH.

The rejection under 112 second paragraph for claims 49, 50-52, 59, 65, 66 are moot in view of the amended claims and interview summary, paper no. 26.

Claims 44, 49, 50, 51, 52, 53, 54, 57 would remain rejected under 102(e) for the reasons of record in paper no. 24 and new claims 70-71 are rejected under 102(e) as anticipated by US patent No. 6,242,569.

Furthermore, it is noted that applicants point out that the examiner only cited claims in his 102(e) rejection (pages 9 and 10 of paper no. 27), however, since there is no interference between the claims (See discussion below), applicants can submit a declaration under 37 CFR 1.131 to obviate the 102(e) rejection.

Furthermore, the claims cannot be considered patentable if they are not supported by the specification (See MPEP 2161). Thus, the applicants' attention is drawn to columns 6, 7, 11, and 12, which teach the fragments of SEQ ID NO: 2. Furthermore, the full sequence of SEQ ID NO: 2 is not recited in any of the claims and is listed on column 19 (and columns 17 and 18) as cited in the office action paper no. 24. Thus, the 102(e) is directed to the specification and claims.

Thus, it is noted that applicants state, "they will file an appropriate declaration under 37 CFR 1.131 in order to obviate the rejection for those claims."

The examiner has discussed the interference and 102(e) issue with an interference specialist. The result of the interview is that there is no interference between the claims of the instant application and Patent No. 6,242,569 for the following reasons: Applicants' claims are directed to a genus and the claims from '569 are directed to a species of the genus claimed by the Applicants. In view of *University of Washington v. Eli Lilly & Co.* (see <http://www.uspto.gov/web/offices/dcom/bpai/its.htm>), a two way test is required for the applicants to invoke an interference. Thus, patent '569 anticipates the claims of the instant application, however, the instant application does not anticipate the species claimed by patent '569. Since the two way test is not evident, the applicants cannot invoke an interference with patent '569.

Continuation of 10. Other: The amendment will be entered for the reasons set forth above and the objection and rejections apply for the reasons of record in paper no. 24 and the reasons set forth above.

This application contains claims 60-61 drawn to an invention non-elected with traverse in Paper No. 16. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The objection to the drawings is withdrawn in view of the interview summary paper no. 26.



DAVE T. NGUYEN  
PRIMARY EXAMINER